REMOVABLE BILIARY STENT

PRIORITY CLAIM

This patent application is a continuation in part of and claims the benefit of priority under 35 U.S.C. § 120 to co-pending U.S. Nonprovisional Application Serial No. 10/288,615, filed November 5, 2002, which is incorporated in its entirety by this reference.

FIELD OF INVENTION

The present invention relates generally to medical devices directed to the prevention of luminal occlusion, and more particularly to stents and methods for making and utilizing these stents in the treatment of both benign and malignant conditions wherein the functionality of the stents is determined by geometrical variability of the scaffolding and concomitant interstices.

BACKGROUND OF THE INVENTION

Stents are devices that are inserted into a vessel or passage to keep the lumen open and prevent closure due to a stricture, external compression, or internal obstruction. In particular, stents are commonly used to keep blood vessels open in the coronary arteries and they are frequently inserted into the ureters to maintain drainage from the kidneys, the bile duct for pancreatic cancer or cholangiocarcinoma or the esophagus for strictures or cancer. Vascular as well as not vascular stenting has evolved significantly; unfortunately there remain significant limitations with respect to the

technology for producing stents suitable to various portions of a patient's anatomy.

Historically, in order to provide a stent with varying characteristics, the stent had to be manufactured from multiple materials, at least one for each characteristic desired. As a result, many of these stents are woven from two or more metals having differing shape-memories for example. Unfortunately, braided stents are vulnerable to premature obsolescence. Moreover, providing multiple material types in a single stent may lead to inconsistent characteristics along the surface area of the stent. This is particularly undesirable when the stent is to be placed in vascular or nonvascular lumens that have been occluded for one reason or another. The stent needs to be stiffer in some regions while more flexible in others.

Additional limitations of existing devices involve the constraint of flow dynamics through the internal diameter because of their scaffolding architecture. In particular, billiary stents can easily become clogged by the stagnation of bile there through depending on exactly where the stent is placed between the liver, the gallbladder and the duodenum.

Therefore, there remains an existing need for a therapeutic stent that can have varying characteristics along its surface area while being stamped, not braded, from a single base material. Moreover, there is a need for such a therapeutic stent where the relative hardness, softness, flexibility, stiffness and radial force can be modified as a function of geometric considerations rather than material considerations. In particular, there is a need for a stent that is divided into zones so as to allow the stent to have predetermined characteristics in one zone and could conceivably have drastically different characteristics in an adjacent zone so as to allow for stents

that can be tailored to anatomical lumens in general and the particular lumen topography of a specific patient in particular. Moreover, a need remains for a stent that is specifically designed to resist adhesion and facilitate the flow of viscid fluids.

SUMMARY OF EXEMPLARY EMBODIMENTS

It is a principal purpose of the present invention to provide a stent, in accordance with an exemplary embodiment of the present invention, which combines many of the excellent characteristics of both silicone and metal stents while eliminating the undesirable ones. In particular, it is an objective of a preferred embodiment in accordance with the present invention to provide a stent that is easily installed, yet in alternative embodiments, removable. Moreover the stent in accordance with this embodiment of the present invention would not cause material infections and may be capable of reducing infection. Therefore, a principal objective of a preferred embodiment in accordance with the present invention is to provide a prosthesis that is suitable for both permanent and temporary use while being easy to insert, reposition and remove.

A principal objective of a preferred embodiment of the present invention is to provide a stent that may be stamped from preferably a single material that is capable of maintaining its axial working length when radially compressed. To this end, the stent does not have a seam that could aggravate luminal tissue. In particular, a stent in accordance with the present invention is formed using a tool that molds the stents outer contour as well as its interstices.

It is yet another objective of an exemplary embodiment of the present invention to provide a stent that can be indicated for the

treatment of benign and malignant disease and improve the way clinicians treat malignant obstructions.

Still another objective of the present invention is to provide a stent and method for installing the stent that is economical and suitable for routine purposes. Moreover, the stent will have minimal migration, cause minimal tissue granulation, will not foreshorten after deployment and mucociliary clearance will not be problematic.

Yet another objective of an exemplary embodiment in accordance with the present invention is to provide a prosthesis that will have superior internal to external diameter ratio, superior radial force with dynamic expansion, while being suitable for use in pediatric and adult patients with malignant and benign disease.

A principal objective of an exemplary stent in accordance with the present invention is to provide a family of stents where the relative hardness/softness of regions of the stent can differ from other regions of the stent to provide additional patient comfort and resistance to radial forces.

An additional objective in accordance with an exemplary embodiment is to provide a family of stents with novel interstice configurations that facilitate flexibility, durability and/or proper installation.

Still another objective of a preferred embodiment of the present invention is to provide a self-expanding stent having the above benefits that also defines a plurality of apertures at the termini of the stent for, *inter alia*, removal of the stent.

An additional objective in accordance with a preferred embodiment of the present invention is to provide a billiary stent specifically designed to facilitate fluid flow dynamics generally and bile flow in particular. In the furtherance of this and other objectives,

a substantially cone shaped billiary stent is provided that harnesses the benefits of fluid mechanics to prevent undesireable obstruction of the stent lumen.

Further objectives, features and advantages of the invention will be apparent from the following detailed description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 shows a side perspective view of an exemplary stent in accordance with the present invention.

FIG. 2 shows a side perspective view of a single zone of the stent shown in FIG. 1.

FIG. 3 shows an enlarged perspective view of the interstices of an exemplary zone as shown in FIG. 2.

FIG. 4 shows an enlarged perspective view of the interstices of an exemplary zone as shown in FIG. 2 showing an alternative octagonal connection member.

FIG. 5 shows an enlarged perspective view of the interstices of an exemplary zone as shown in FIG. 2 showing an alternative omega shaped connection member.

FIG. 6 shows an enlarged perspective view of the interstices of an exemplary zone as shown in FIG. 2 showing an alternative M shaped connection member.

FIG. 7 shows an enlarged perspective view of the interstices of an exemplary zone as shown in FIG. 2 showing an alternative S shaped connection member.

FIG. 8 shows a magnified view of the scaffolding and interstice topology of the medical appliance shown in FIG. 1.

FIG. 9 shows a magnified portion of the scaffolding and interstice topology of the medical appliance of FIG. 1, showing how modifications in geometric dimensions affect functionality.

FIG. 10 shows an enlarged perspective view of an exemplary connector wherein the connector is oriented closer to one zone than another.

FIG. 11 shows an enlarged perspective view of an exemplary connector wherein the connector is oriented closer to the opposite zone as the connector shown in FIG. 10.

FIG. 12 shows an enlarged perspective view of an exemplary connector wherein the connector is oriented substantially equidistant between two zones.

FIG. 13 is a perspective view of a substantially cone shaped biliary stent in accordance with the present invention.

FIG. 14 is aerial view of the stent of FIG. 13 along line 14 – 14, showing the lumen thereof and the dimensional mismatch between the lumen diameter at the proximal and distal ends of the stent.

FIG. 15 is an aerial view of the stent of FIG. 13 from the opposite end of that shown in FIG. 14.

DETAILED DESCRIPTION OF AN EMBODIMENT

A preferred embodiment of the stent, in accordance with the present invention, provides a stent that prevents epithelialization of the stent and is not subject to premature elongation and foreshortening but is capable of engaging the desired implantation location. The stent also retains its axial length while undergoing radial compression.

The stent is preferably formed from a composite material selected from the group consisting essentially of Ni, C, Co, Cu, Cr, H,

Fe, Nb, O, Ti and combinations thereof. The composite material is generally formed into a compressed tube from which the stent is etched and is formed on a suitable shaping device to give the stent the desired external geometry. Both the synthetic collar techniques and in vitro valuation techniques show the remarkable ability of stents in accordance with the present invention to convert acting force into deformation work absorbed by the angled structure, which prevents excessive scaffolding stress and premature material fatigue and accelerated obsolescence.

Though one skilled in the stent engineering art, once apprised of the present application, would be able to manufacture a stent consistent with the present invention by other methods, a preferred method of manufacturing such stents follows. As stated above a composite material is selected and a blank is formed there from. The blank is preferably laser etched and the etch work is generally verified for accuracy using visual recording microscopy. Dimensional measurements are taken to ensure strut thickness, segment angles, zone placement, etc. Moreover, the stent is preferably formed on a shaping tool that has substantially the desired contour of the external stent dimensions.

In the event the stent is to be shaped to the dimensions of a particular lumen, optical photography and/or optical videography of the target lumen may be conducted prior to stent formation. The geometry of corresponding zones and connector regions of the stent then can be etched and formed in accordance with the requirements of that target lumen. For example, if the stent were designed for the trachea, which has a substantially D shaped lumen and additionally the middle zones needed to be softer than the end zones, the stent could be designed to those specifications. In particular, if the

topography of the trachea of a particular patient is captured optically and the appropriate dimension provided, a patient specific prosthesis could be engineered. These techniques can be adapted to other non-vascular lumen but is very well suited for vascular applications where patient specific topography is a function of a variety of factors such as genetics, lifestyle, etc.

It should be pointed out that unlike the use of differing shape memory materials to change regions of a stent, stents in accordance with the present invention can take on an infinite number of characteristic combinations as zones and segments within a zone can be modified by changing angles, segment lengths and segment thicknesses during the etching and forming stages of stent engineering or during post formation processing and polishing steps. Moreover, by modifying the geometry of the connectors between zones, addition functionality may be achieved.

Exemplary stents 10 in accordance with the present invention are shown in FIGS. 1-3 showing the preferred interstice geometry. Not shown are a wide variety of interstice geometries that are also acceptable alternatives to the preferred, namely, U, V, W, Z, S and X geometries to name a few.

The stent 10 also is formed of memory metal and preferably has unique geometrical interstices that are laser etched therein. However, other conventional ways of forming interstices in unitary stents, though not equivalent are contemplated, may be employed and would be within the skill set of one in the art.

It cannot be overemphasized, however, that this does not mean the knowledge that changes in the geometry of interstices affect stent functionality is currently known in the art. To the contrary, the present inventors discovered the interrelation between interstice

geometry, width, length and relative resistance to torsional stress and radial force. In fact, it can be said that the stent 10 has circumferential bands extending perpendicularly with respect to the luminal device's longitudinal axis. These bands are referred to generally as zones. A connector 50 connects these bands to one another; the connector 50 is an additional means for adjusting stent functionality. In particular, the connector 50 defines a substantially U shaped member, but could define other geometries such as U, V, W, Z, S and X to name a few.

In a standard orientation, as shown particularly in FIG. 1, the substantially U-shape connector comprises preferably two leg members 52 & 56 and a crossing member 54 that connects with and extends perpendicularly at preferably 90° angles with respect to the leg members 52 & 56. It must be noted that alternative angles may be provided without departing materially from the invention. The present inventors discovered that if you modify the length of the crossing member 54 and/or the leg members 52 & 56 and/or the angle γ at which the crossing member 54 and the leg members 52 & 56 intersect, the relative hardness/softness, radial force and/or flexibility of the stent 10 could be modified. The angles γ can be modified at varying acute angles short of 90° or varying obtuse angles greater than 90°. The incremental changes correspondingly change certain characteristics of the stent 10. As a result, different zones of the stent 10 can be given different rigidities to improve patient comfort and for example, in airway stents, to facilitate luminal patency. Moreover, various anatomical lumens may need different degrees of stent rigidity. As a result, stents 10 in accordance with the present invention can be manufactured to exacting specifications to contour

properly to various lumens in a patient's anatomy, which may need varying levels of structural support from the medical appliance.

As depicted in FIGS. 10-12, by adjusting the distance between the connector 50 and for examples Zones 2 and 3 between which connector 50 resides, the way in which the stent reacts to strain can be modified. By way of non-limiting example, if the connector 40 is oriented closer to zone 3 than to zone 2, the stent will be less flexible and be able to withstand greater radial force. Alternatively, if the connector is equidistant between Zones 2 and 3, the stent will be more flexible and be able to withstand less radial force. Please note that these differences are relative to a neutrally located connector 40. The behavior is a function of distance and as a result varies along a continuum with respect to the connector's orientation between the medium between zones and the tip of each zone. Moreover, within by varying the number of connectors 40 that connect the zones to one another, functionality can be impacted. In particular, the fewer the number of connectors connecting the zones the more torsional flexibility the stent will have. The converse will generally hold true with respect to a greater number of connectors.

Referring now to FIG. 2, stent 10 is shown having several bands within a zone forming substantially arrow shaped regions. In particular, each arrow shaped band preferably comprises a forward angle β and a rear angle α. The forward angle β is formed by the intersection of two legs 24 & 25. Legs 24 & 25 connect at first ends 26 & 27 to form the head 22 of angle β. Second ends 28 & 29 of legs 24 & 25 terminate at connectors 40. Connector 40 connects the legs 24 & 25 of forward angle β to the legs 32 & 34 of rear angle α via intermediary leg 36.

Where legs 32, 34 & 36 connect is the head 30, which defines an aperture 38 for installing suture.

Connector 40, which serves a similar purpose as connector 50 also has a crossing member 44 that connects leg members 42 & 46 at a predetermined angle δ. As discussed above, since form follows function for stents prepared through this novel method, by changing the degrees of angles α, β, δ & γ, stent characteristics can be modified. Moreover, by changing the leg lengths of all the previously discussed legs or individual legs separately, additional stent characteristics can be obtained. The beauty of this system is that the desired characteristics can be determined prior to forming the stent and by staying within certain forming parameters, the stent can be formed, crimped, delivered and deployed with confidence that the desired functionality with result. This is important in light of the fact that both vascular and nonvascular lumen have unique topography. As a result, methods and devices in accordance with the present invention usher in the ability to tailor prosthesis to anatomical tissue in general and particular patient anatomy in particular.

The U shaped connectors 40 & 50 have a crossing member and at least two leg members, respectively. The present inventors discovered that if you increase/decrease the length of leg members and/or increase/decrease the length of crossing members and/or vary the angle at which crossing members and leg members intersect, you affect the functionality of the stent. In particular, the shorter the length of the leg members, the less flexibility available in that portion of the stent. Taking particular note of FIG. 3, by way of example only, if you want to decrease the amount of torsional flexibility of the stent 10, you would have to modify the connector 40 so that the legs 42 & 46 are longer than shown and that the angle δ formed by legs 42 & 46

and crossing member 44, respectively, is slightly greater than 90°. Alternatively, the length of the crossing member 44 can impact the functionality of the stent as well. The stent can be made more rigid by shortening crossing member 44 or the stent may be made more flexible by lengthening crossing member 44. It should be noted that the combination of the changes of leg lengths, crossing member lengths, angle variations, shapes and number of connectors provide the stent with the ability to conform to specific lumens in the anatomy of a patient. The result is a form fitting medical prosthesis that may be tailored to specific anatomical lumens in general and to the anatomical lumens of an individual patient in particular.

In a preferred embodiment, the modification of interstice geometries and manipulation of the U shaped connection member to achieve variable stent functionality is provided. The rigidity of the stent scaffolding or interstice matrix along with the torsionality of the stent itself is principally a function of these modifications. In an exemplary embodiment, the stents relative flexibility can be rated soft, medium or hard based on the degree of flex and torsionality. The less torsionality and flex in the stent the harder the stent is rated.

An exemplary stent in accordance with the present invention with relatively great torsionality and radial flexibility would be rated soft. An exemplary soft rated stent comprises distance between U shaped connectors of about 4.5 μm in the compressed state (i.e., contracted in the 3mm tube subject to laser etching). Moreover, the length of the crossing member is preferably about 1.0 μm. The lengths of the leg members are preferably about 1.5 μm in length. Additionally the leg members may further comprise feet that attached to the remainder of the stent scaffolding. The feet can be

adjusted from a standard length of about 0.25 μm to further adjust the characteristics of the stent. There is additionally a substantially rectangular member incorporated in the U shaped connector with similar capacity for variability. The variability factors and results of modifying the dimensions of the substantially rectangular members are similar to those evinced by leg length dimensional modifications.

Referring now to FIGS. 8 and 9, where like numerals refer to like parts, luminal stent 810 is shown having substantially U shaped connectors 818 having a crossing member 819a and at least two leg members 819b-c respectively. The present inventors discovered that if you increase/decrease the length of leg member 819b and/or 819c, increase/decrease the length of crossing member 819a, and/or vary the angle at which crossing member 819a and leg members 819b-c intersect, you affect the functionality of the stent. In particular, the shorter the length of leg members 819a-b the less flexibility available in that portion of the stent. Taking particular note of FIG. 9, by way of example only, if you want to decrease the amount of torsional flexibility of the luminal stent 910, you would have to modify the desired portion of the stent to resemble 918f. However, if you want a stiffer appliance 910, you would have a configuration analogous to that of 918a.

By way of example, but not to be construed in any way as limiting, the softness index or relative flexibility can be increase by increasing the various lengths discussed above. For example, by increasing the length of the legs and crossing members of the U shaped connector, flexibility increases. However, with respect to the distance between U shaped members and distance between interstices in a preferred stent embodiment, there is an inverse correlation between length and softness. This relative

softness/hardness indexing as a corollary of interstice dimensions is a novel aspect of preferred embodiment of the present invention. As a practical rule of thumb, longer leg lengths coupled with acute angles provide for greater flexibility. Conversely, shorter leg lengths and more obtuse angles provide more rigidity. By way of non-limiting example, a U shaped connector with short legs deviating from the crossing member at angles greater than 90°, will be extremely rigid and resistant to torsional strain as compared to a U shaped connector with longer legs diverging from the crossing member at angles less than 90°.

In addition to the length and spacing differences, the interstices themselves may define various shapes that by their very nature afford novel functionality to the stent. The changes of functionality, however, are more a function of the dimensional differences of the various shapes rather than a function of the shapes themselves. Therefore, it is important to keep in mind that the dimensional differences discussed in the previous paragraph are determinative of the functionality accorded the stent by the varying interstice geometries. It is for this reason that one of ordinary skill in the art, after being apprised of the present invention, would be able to conceive of a number of interstice geometries to satisfy certain functionality criteria by keeping certain dimensional parameters constant.

Experiments have shown that viscid fluids such as bile can be very adhesive in implantable devices due to charge, density and drag coefficient. The drag exerted on the stent scaffolding from moving fluid is directly proportional to the density of the fluid. Density describes the mass per unit volume. Therefore, the density of bile increases the likelihood that it can become stagnant in a stented lumen. As a result, the present inventors harnessed principles of fluid

mechanics to develop a stent that can reduce drag by facilitating the flow rate of the fluid and the surface area of evacuation.

Making specific reference to FIGS. 13-15, an exemplary stent in accordance with the present invention provides a substantially cone shaped scaffolding to facilitate bile flow. In particular, the distal end of the stent has a larger lumen diameter than the proximal end. However, it should be noted that in preferred embodiments the distal end still has a lumen diameter that is less than the greatest lumen diameter along the device. In other words, the distal end is oriented inward toward the lumen such that the ends do not necessarily come into contact with tissue in order to facilitate removability.

Moreover, removability is enhanced by providing apertures 30 and 120 defining eyelets through which suture may be threaded in order to purse string the stent for easier removal. The eyelets are preferably large enough to receive between 6-0 and 4-0 suture. It should also be noted that the eyelets 30 and 120, though shown at the distal and proximal ends of the stent may be configured along the longitudinal expanse there between in order to vary the degree of radial compression used to remove the stent.

As an adjunct to the biliary stent, in cases where the stent is placed in the lower intestinal tract, an annular ring should be provided to prevent regeneration and obstruction at the Sphincter of Oddi. In many cases, the Sphincter of Oddi is dilated, burned or made inoperable by various means in order to alleviate an obstruction and to facilitate stenting. Unfortunately, the sphincter often grows back or regenerates in some fashion that causes problems for the patient. By providing an annular ring to keep the lumen open, the efficacy of stenting is enhanced.

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative, and not restrictive. The scope of the invention is, therefore, indicated by the appended claims, rather than by the foregoing description. All changes, which come within the meaning and range of equivalency of the claims, are to be embraced within their scope.